

31 OCT 2004

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date
6 November 2003 (06.11.2003)

PCT

(10) International Publication Number
WO 2003/090693 A3

- (51) International Patent Classification⁷: A61K 9/14, 31/53 (74) Agent: BRAINARD, Charles, R.; Kenyon & Kenyon, One Broadway, New York, NY 10004-1050 (US).
- (21) International Application Number:
PCT/US2003/013002
- (22) International Filing Date: 23 April 2003 (23.04.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/374,923 23 April 2002 (23.04.2002) US
- (71) Applicant (for all designated States except BB, US): TEVA PHARMACEUTICAL INDUSTRIES LTD. [IL/IL]; 5 Basel Street, P.O. Box 3190, 49131 Petah Tiqva (IL).
- (71) Applicant (for BB only): TEVA PHARMACEUTICALS USA, INC. [US/US]; 1090 Horsham Road, P.O. Box 1090, North Wales, PA 19454-1090 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): ARONHIME, Judith [IL/IL]; Rehov Harav Maor, Josef 5a, 76217 Rehovot (IL). SAMBURSKI, Guy [IL/IL]; Hairusim 19, 42930 Ganot-Hadar (IL).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(88) Date of publication of the international search report:
8 January 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2003/090693 A3

(54) Title: PHARMACEUTICAL COMPOSITION CONTAINING LAMOTRIGINE PARTICLES OF DEFINED MORPHOLOGY

(57) Abstract: The present invention provides a pharmaceutical composition comprising a plurality of lamotrigine particles having a specific surface area of from about two to about three and a half meters per gram. Pharmaceutical compositions falling within the surface area criteria for the lamotrigine particles include those having a particle diameter equal to or less than about 100 µm, preferably about 50 µm, and most preferably 10 µm. The pharmaceutical composition can be formulated into a wide variety of dosage forms.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2003/13002

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/14 A61K31/53

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 17611 A (WELLCOME FOUND ;HISKETT SIMON PHILIP (GB); TAYLOR SUSAN ANN (GB)) 13 June 1996 (1996-06-13) cited in the application page 5, line 25 - line 27 example 1 ---	1-26
Y	ES 8 604 019 A (NIPPON SHINYAKU CO LTD) 1 June 1986 (1986-06-01) page 1, line 13 - line 22 page 6, line 29 -page 7, line 14 page 9, line 9 - line 29 examples ---	1-26 -/-

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

° Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the International filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed Invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed Invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

4 August 2003

23/10/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP03/13002

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 00681 A (WELLCOME FOUND ;FLOYD ALISON GREEN (US); JAIN SUNIL (US)) 9 January 1997 (1997-01-09) cited in the application examples ----	1-26
A	WO 01 22938 A (VERRECK GEERT ;BAERT LIEVEN (BE); JANSSEN PHARMACEUTICA NV (BE)) 5 April 2001 (2001-04-05) page 39, line 17 - line 34 page 41, line 7 - line 8 page 75, line 11 - line 18 -----	1-26

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US 03/13002**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 25, 26 because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 25 and 26 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Claims Nos.: 25,26

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte nal Application No

PCT/US 03/13002

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9617611	A	13-06-1996		AT 213633 T AU 696406 B2 AU 4121196 A BR 9509975 A CA 2207284 A1 CN 1174505 A CZ 9701717 A3 DE 69525649 D1 DE 69525649 T2 EP 0797441 A1 ES 2172600 T3 FI 972434 A WO 9617611 A1 HU 77367 A2 JP 2977284 B2 JP 10510255 T NO 972623 A NZ 296573 A PL 320560 A1 RU 2160106 C2 US 5861179 A		15-03-2002 10-09-1998 26-06-1996 09-06-1998 13-06-1996 25-02-1998 12-11-1997 04-04-2002 05-09-2002 01-10-1997 01-10-2002 09-06-1997 13-06-1996 30-03-1998 15-11-1999 06-10-1998 06-08-1997 22-08-1997 13-10-1997 10-12-2000 19-01-1999
ES 8604019	A	01-06-1986	ES	8604019 A1		01-06-1986
WO 9700681	A	09-01-1997		AT 228844 T AU 6415796 A DE 69625200 D1 DK 833640 T3 WO 9700681 A1 EP 0833640 A1 ES 2188766 T3 JP 11507936 T PT 833640 T US 5942510 A		15-12-2002 22-01-1997 16-01-2003 24-03-2003 09-01-1997 08-04-1998 01-07-2003 13-07-1999 30-04-2003 24-08-1999
WO 0122938	A	05-04-2001		AU 1046200 A AU 7512700 A BG 105419 A BG 106521 A BR 0014271 A BR 9915176 A CA 2351203 A1 CA 2384188 A1 CN 1376057 T CN 1325387 T CZ 20011532 A3 CZ 20020907 A3 EE 200100253 A EE 200200151 A WO 0122938 A1 WO 0027828 A2 EP 1225874 A1 EP 1129079 A2 HR 20010310 A1 HU 0104395 A2 HU 0203568 A2 JP 2002529457 T JP 2003510264 T		29-05-2000 30-04-2001 30-11-2001 29-12-2002 21-05-2002 14-08-2001 18-05-2000 05-04-2001 23-10-2002 05-12-2001 17-10-2001 15-05-2002 16-12-2002 15-04-2003 05-04-2001 18-05-2000 31-07-2002 05-09-2001 30-06-2002 29-04-2002 28-02-2003 10-09-2002 18-03-2003

INTERNATIONAL SEARCH REPORT
Information on patent family members

Inte [REDACTED]inal Application No
PCT/US [REDACTED]3/13002

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 0122938	A	NO	20011934 A	19-04-2001
		NO	20021443 A	22-03-2002
		NZ	517025 A	25-07-2003
		PL	348145 A1	06-05-2002
		SK	3762002 A3	10-09-2002
		SK	6022001 A3	07-01-2002
		TR	200101319 T2	22-10-2001